49. The method of Claim 40 further comprising the step of: allowing excess methylene blue to leach into the container in which the body fluid is stored after mixture with the methylene blue.

50. The method of Claim 40 wherein the light field is generated by at least one array of light emitting diodes.

51. The method of Claim 40 wherein the mixture is irradiated by the light field for a cumulative period of at least five minutes.

REMARKS

This Amendment is submitted in response to the Office Action mailed on July 30, 2001. The Office Action rejects Claims 28-39 under 35 U.S.C. § 103 and 112. Pursuant to this Amendment, Claims 28 and 30 have been amended, Claims 31, 33, 35 and 37 have been cancelled, and Claims 40-51 have been added. For the reasons set forth below, the rejections have either been overcome or, Applicants respectfully submit, are not proper.

At the outset, it is important to note that the above-identified patent application is a continuation of U.S. Patent Application Serial No. 08/350,398. Applicants believe that a couple of the issues that are raised in the present Office Action appear to have been addressed by the Board of Appeals for the Patent Office in the parent application. For the convenience of the Examiner, enclosed is a copy of the Board's decision.

Initially, the Patent Office rejects Claims 28-39 under 35 U.S.C. § 112 stating that the term "body fluid" is contradictory and not proper. At the outset, Applicants question why the Patent Office is raising this issue for the first time when this issue was not raised during the

prosecution of the parent application, which used the identical term. In fact, the Board of Appeals which reviewed claims including the term "body fluid" found no issue with respect to use of this term.

Applicants respectfully submit that use of the term "body fluid" is entirely proper. Indeed, it appears the only way the Patent Office can craft a § 112 rejection with respect to this term is by attempting to distort how Applicants are using the term. In this regard, the Patent Office states that Applicants refer to body fluid as including an internal organ, citing page 8 of Applicants' specification. On page 8, Applicants actually state that a body fluid can be a "fluid containing structures such as internal organs." It is not an organ Applicants are claiming can constitute a body fluid but, a fluid containing an internal organ.

As admitted by the Office Action, Applicants have defined the term "body fluid" but, the Patent Office states that "Applicant cannot define a term in opposition to a generally-accepted definition." The Patent Office states that clearly, red cells, white cells, and platelets are not body fluids. However, U.S. Patent No. 5,030,200, that the Patent Office has cited in this Office Action, defines the term "body fluid" in part, as including whole blood and any formed elements of the blood (see column 8, line 10). Indeed, the Oxford Dictionary of Science defines body fluid as "any of the fluids found within animals, including blood, lymph, tissue fluid, urine, bile, sweat and synovial fluid." See Exhibit A. Thus, contrary to the assertion of the Patent Office, Applicants are using the term in accordance with its generally-accepted definition. Therefore, Applicants respectfully request that the rejection of Claims 28-39 under 35 U.S.C. § 112 for use of the term "body fluid" be withdrawn.

The Patent Office rejects Claim 28 stating that the claim requires that the container that contains the body fluid is made of PVC and also requires that the inner surface of the container

be made of a non-PVC material. The Patent Office states this appears to be a contradiction, if the container is made of PVC, it cannot have non-PVC materials. Applicants have amended the claim so that it claims a container including a PVC portion and an inner layer of non-PVC. Therefore, Applicants respectfully submit that the rejection has been overcome.

The Patent Office also objected to the word "plastic" in Claim 28 stating that it is unclear whether it is meant to modify PVC or if the container is a plastic which is not a PVC-type material. Applicants have amended the claim as suggested by the Office Action and accordingly this rejection has been overcome.

Claim 30 has been rejected because there is no antecedent basis for the term "blood component". Claim 30 has been amended to depend from Claim 29 and accordingly antecedent basis is provided.

Claim 31 has been rejected as being unclear. In the spirit of cooperation, Claim 31 has been canceled without prejudice or disclaimer.

Claim 33 has been rejected under 35 U.S.C. § 112. In the spirit of cooperation, Claim 33 has been canceled without prejudice or disclaimer.

The Patent Office states that Claim 35 appears redundant. Accordingly, in the spirit of cooperation, Claim 35 has been cancelled.

Claim 37 has been rejected as being contradictory. In the spirit of cooperation, Claim 37 has been canceled without prejudice or disclaimer.

The Patent Office also rejects Claims 28-39 under 35 U.S.C. § 112 stating that insertion of the limitation "sterile, sealed containers, each container having an inner surface of a non-polyvinylchloride plastic" has no support in the specification. Applicants respectfully disagree.

Of course, the test for new matter under 35 U.S.C. § 112 is not whether or not the concept is explicitly set forth verbatim. *In re Kaslow*, 707 F.2d 1366 (Fed.Cir. 1983). The test is whether one would believe Applicants were in possession of the concept at the time the application was filed. *In re Alton*, 76 F.3d 1168 (Fed.Cir. 1996).

A review of the specification clearly demonstrates Applicants were in possession of the claimed concept. The specification is complete with a discussion that at least the layer contacting the methylene blue solution is of a non-PVC material. See, for example, page 9, lines 20-26. With respect to the blood container, this container is discussed on, for example, page 10. As stated therein, the container 10 can have a structure that is substantially similar to a container for housing blood and blood components available from the Fenwal Division of Baxter however, the container can also be constructed so that at least an inner layer that defines the interior surface of the container is constructed from a non-PVC material. This type of container can also be used to house methylene blue alone. See page 10, lines 14-21. At the bottom of the page beginning at line 27 is a further statement that, pursuant to the present invention, a body fluid such as a blood component and a therapeutically effective amount of methylene blue are mixed together in the container 10. In one embodiment, methylene blue is added to the body fluid already stored in the container 10. Thus, page 10 specifically advises those reading it that the methylene blue can be stored in a container having a non-PVC layer and blood can be stored in the container 10 having a non-PVC material. It is also stated that these components can be mixed together.

With respect to the concept of separate sterile containers, as set forth on page 11, the components can be separately sterilized. Of course, such separate sterilization would provide methylene blue and a body fluid in a separate sterile container.

Thus, the concepts of storing the body fluid and the methylene blue in separate containers having an inner surface of a non-polyvinylchloride plastic material are disclosed. The concepts of sterilizing the containers are disclosed. Of course, the containers have to be sealed as one skilled in the art would know.

Therefore, Applicants respectfully submit that clearly the claimed concepts that the Patent Office has objected to as new matter are clearly disclosed or would be readily apparent to one skilled in the art reading the specification. Therefore, Applicants respectfully request the rejection be withdrawn.

The Patent Office then rejects Claims 28-39 under 35 U.S.C. § 112 based on alleged enablement. Applicants respectfully submit that this rejection is not proper. Applicants believe that the issues present in the rejection were dealt with by the Patent Office in the Board of Appeals decision and therefore, Applicants respectfully request the rejection be withdrawn for the reasons set forth by the Board of Appeals. For example, the Office Action states, "the specification fails to describe the concentration of methylene blue that should be added to the body fluid..." The Board of Appeals specifically held that in response to the Patent Office's previous rejection of lack of enablement because the amount of methylene blue to be added was not described that the disclosure of the specification was enabling.

Further, the Board noted that the Examiner's own art stated that this information has been available for fifty years. See Board Opinion, pages 7 and 8. Thus, the art is not as unpredictable as asserted by the Patent Office. The Board specifically held that procedures to inactivate viruses have been known for a long time. See page 8 of the Board's decision. Applicants respectfully submit that Applicants' specification when interpreted properly in view of the state of the art clearly provides enablement.

Claims 28-39 stand rejected under 35 U.S.C. § 103 as being unpatentable over *Lambrecht*, *Mohr* in combination with *Wallvick*, or *Rock* or U.S. Patent No. 4,726,949 or 5,030,200. Applicants respectfully submit that this rejection is not proper. Applicants respectfully submit that not one of the cited references discloses or suggests the concept of using a plastic container including a non-PVC layer in combination with methylene blue. The claims have specifically been amended to require plastic container for storing the methylene blue.

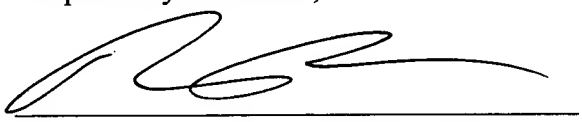
Applicants respectfully submit that the only reason the Board of Appeals affirmed a similar rejection in the parent application was because the claims on appeal did not require a plastic container. Therefore the Board reasoned that the claims could read on a container such as *Mohr* that was made of glass.

In contrast to the claims that were on appeal, all of the pending claims require a plastic container. Applicants therefore respectfully submit that the rejection is therefore not proper and not supported by the Board's decision. The references, either alone or in combination, fail to disclose Applicants' claimed concept of storing and sterilizing methylene blue in a container that includes as the layer that contacts the methylene blue a non-PVC plastic. Nor is there any motivation to so modify *Mohr*. The references fail to disclose or suggest any issue or problem with storing or sterilizing a solution of methylene blue in contact with PVC plastic. Therefore, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 103 be withdrawn.

Applicants are submitting herewith newly-submitted Claims 40-51 that Applicants submit are allowable over the art. Notice to that effect is respectfully requested.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

28. A method for inactivating viruses in a body fluid, the method comprising the steps of:

initially storing an amount of methylene blue and an amount of the body fluid in separate sterile, sealed containers, each container having an inner surface made of a non-polyvinyl chloride, plastic material and the container in which the body fluid is stored ~~is~~ includes portions that are made of a polyvinyl chloride material;

forming a mixture by adding at least a portion of the amount of the methylene blue to the amount of the body fluid wherein the portion of methylene blue is a virucidally effective amount of the methylene blue and further wherein the mixture formed is within one of the containers in which the methylene blue or body fluid is initially stored under sterile conditions; and

irradiating the mixture with a light field of a suitable intensity and wavelength for activating the methylene blue for a time sufficient to inactivate viruses in the mixture, while maintaining the mixture under a substantially no flow condition within the container in which the mixture is formed.

30. The method of Claim ~~28~~ 29 wherein the blood component is selected from the group consisting of: plasma, red blood cells, white blood cells, and platelets.

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